

Antibody Profiles in Pemphigoid (APP)

Submission date 10/04/2019	Recruitment status Suspended	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/08/2020	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims:

Bullous pemphigoid is a rare blistering disorder where the immune system attacks part of the skin. Our goal is to find out more about the causes of bullous pemphigoid and in particular, why the condition affects different people in different ways. We know that bullous pemphigoid is caused by the immune system damaging part of the skin. We do not usually know the trigger for this, although in some people it may be a medication that they have taken. Bullous pemphigoid can look very different from person to person – some may have lots of redness with just a few (or no) blisters, and some may only have widespread blisters but little redness. Some may have both. A recent study in Japan suggested that people with forms of bullous pemphigoid that look different to one another may have damage to different parts of the skin. It is also thought that where a medication is causing bullous pemphigoid, this may look different or give different blood test results. Our study will look into whether adults in the UK also get different types of bullous pemphigoid depending on which part of the skin is affected. We will also look if there are other things that might explain any differences, such as medications that have been taken recently, or underlying differences in the immune system.

Who can participate?

Adults with a diagnosis of active bullous pemphigoid.

What does the study involve?

The study involves a blood test to look in detail at how the immune system is damaging the skin.

What are the possible benefits and risks of participating?

The treatment that a patient receives will not be any different if they take part in the study. The potential risk of physical harm from taking part in the study is that of an additional blood test i.e. a small amount of pain or discomfort and the possibility of bruising.

Where is the study run from?

The study is run from the Leicester Royal Infirmary.

When is the study starting and how long is it expected to run for?

The study will start in August 2019 and is expected to run for up to 2 years.

Who is funding the study?

The study is funded by the University Hospitals of Leicester Dermatology Research Fund.

Who is the main contact?

1. Dr Matthew Scorer (public & scientific contact), matthew.scorer@nhs.net

2. Dr Karen Harman (scientific contact), karen.harman@uhl-tr.nhs.uk

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

112816

Study information

Scientific Title

Antibody Profiles in Inflammatory and Non-Inflammatory Bullous Pemphigoid

Acronym

APP

Study objectives

Auto-antibody profile correlates with clinical phenotype in bullous pemphigoid

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/01/2020, West Midlands - Coventry & Warwickshire Research Ethics Committee
(The Old Chapel, Royal Standard Place, Nottingham HRA1 Meeting Room, NG1 6FS, UK; +44 (0)
207 104 8009; NRESCcommittee.WestMidlands-CoventryandWarwick@nhs.net), ref: 19/WM/0292

Study design

Single-centre cross-sectional observational study.

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Bullous pemphigoid

Interventions

The study design is a cross-sectional observational study of patients newly diagnosed with bullous pemphigoid. Patients with clinically suspected bullous pemphigoid will be referred from dermatology clinics or triaged from referral letters. There will be one study visit which will replace the first clinic visit and will include a clinical history, physical examination and assessment with a validated scoring system for documenting clinical findings in bullous pemphigoid (the Bullous Pemphigoid Disease Area Index (BPDAI), venepuncture for blood samples (both usual care investigations and for research purposes), and a skin biopsy under local anaesthetic. The patients will then be followed up with usual care in general dermatology clinics.

Intervention Type

Other

Primary outcome measure

BPDAI score in two groups: patients with circulating autoantibodies to the juxtamembranous extracellular noncollagenous 16A domain (NC16A) of COL17; versus patients with circulating antibodies to Full COL17 without NC16A, measured by ELISA at baseline.

Secondary outcome measures

1. Relative frequency of HLA types and prior exposure to drugs, including DPP-4 inhibitors or other drug classes known to be associated with bullous pemphigoid, in different immunophenotype groups.

We will perform and compare the following tests at baseline assessment:

1.1 HLA type

1.2 Immunoblotting

1.3 Dot blotting

1.4 BP230 ELISA

Overall study start date

07/08/2017

Completion date

05/08/2021

Eligibility

Key inclusion criteria

1. Willing and able to give informed consent for participation in the study.
2. Aged 18 years or above.
3. Clinical diagnosis of suspected bullous pemphigoid.
4. Direct immunofluorescence on skin biopsy (which is performed as part of usual care) demonstrating linear deposition of IgG and/or C3 at the basement membrane zone reported within 8 weeks of enrolment.
5. Able (in the Investigators' opinion) and willing to comply with all study requirements.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

22

Key exclusion criteria

1. Alternative diagnosis to bullous pemphigoid at review by a dermatologist.
2. Skin biopsy is judged to be contraindicated for clinical reasons by the Investigator.
3. Direct immunofluorescence of a skin biopsy fails to demonstrate linear deposition of IgG or C3 at the basement membrane zone within 8 weeks of enrolment.

Date of first enrolment

08/09/2020

Date of final enrolment

05/08/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals of Leicester
Infirmary Square

Leicester
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LE1 5WW

Sponsor information

Organisation

University Hospitals of Leicester

Sponsor details

Research Office, Trust HQ, Level 3 Balmoral Building, Leicester Royal Infirmary
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Sponsor type

Hospital/treatment centre

Website

<https://www.leicestersresearch.nhs.uk/>

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospitals of Leicester NHS Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Results and Publications

Publication and dissemination plan

The results will be submitted for publication to a peer reviewed medical journal and/or presentation at an appropriate international congress.

Intention to publish date

05/08/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Karen Harman (Chief Investigator), available from the email karen.harman@uhl-tr.nhs.uk. The data will be anonymised participant level data on primary and secondary outcome measures, available from the trial end date for a period of 5 years, for the purposes of regulatory review as specified in the participant information sheet and agreed by participants at the time of consent.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No